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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/829,316	04/21/2004	Joel R. Studin	SDF 04-14	5671

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EXAMINER	
SHEIKH, HUMERA N	

ART UNIT	PAPER NUMBER
1618	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/829,316	STUDIN, JOEL R.	
	Examiner	Art Unit	
	Humera N. Sheikh	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 May 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16 and 30-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16 and 30-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt of the Response and Applicant's Arguments/Remarks filed 05/07/08 is acknowledged.

Claims 1-16 and 30-32 are pending in this action. No amendments to the claims have been made. Claims 17-29 and 33-54 have previously been cancelled. Claims 1-16 and 30-32 remain rejected.

* * * * *

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-16 and 30-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Youssefyeh *et al.* (U.S. Pat. No. 5,968,519), (hereafter "Youssefyeh") in view of Lee (U.S. Pat. No. 5,552,162).

Youssefyeh *et al.* ('519) teach a method for the treatment of inflammation and pain associated with inflammatory dermatoses (eczema, urticaria, psoriasis, erythema), gingivitis and acute injury with a composition of finely divided powder of safflower seed or its extract contained in a pharmaceutically acceptable carrier (see Abstract); (column 1, lines 10-18). Youssefyeh teach that the method of treatment for the relief of inflammation and/or pain associated with inflammatory dermatoses such as eczema, urticaria, psoriasis and the like comprises topically administering a therapeutically effective amount of a finely divided powder

of safflower seed or its extract sufficient to induce alleviation of signs, symptoms or causes of inflammation or pain in a pharmaceutically acceptable carrier (col. 11, line 49 – col. 12, line 58); (col. 13, line 53 – col. 14, line 7); (col. 22, line 64 – col. 24, line 13). Youssefyeh teach that for topical administration, the compositions may contain certain pharmaceutical and therapeutical agents either singularly or in combination of which suitable pharmaceutical/therapeutical agents disclosed include anti-inflammatory corticosteroids, such as progesterone, hydrocortisone, prednisone, triamcinolone and dexamethasone. Additional agents disclosed include anti-inflammatory analgesics, local anesthetics, antibacterial agents and antiseptic agents. It is also taught that the topical compositions can be in the forms of ointments, creams, lotions, solutions, dressings and patches and slow-release preparations and film-forming preparations (col. 14, lines 19-40); (col. 15, lines 29-60).

Topical formulations can be prepared by combining the finely divided safflower seed or its extract with conventional pharmaceutical carriers or diluents used in topical dry, liquid and cream formulations. Ointments and creams may be formulated with an aqueous or oil base with the addition of suitable thickening or gelling agents (col. 15, lines 29-60). Ointments, pastes, creams and gels may contain excipients such as cellulose derivatives and silicones (col. 15, lines 43-46).

A preferred form of topical delivery is film-forming materials loaded with finely divided powder of safflower seed or its extract. Suitable film-forming materials taught include cellulosic derivatives, such as methylcellulose, hydroxyethyl cellulose, hydroxypropyl cellulose and other synthetic polymers (col. 15, line 61 – col. 17, line 19); and claim 12. Upon application, the formulation is deposited on the desired area and allowed to form a film, which by the presence of

water in the skin environment, will allow slow delivery of the active agent onto the area being treated (col. 17, lines 20-23).

Applicants claim, "hardening the carrier into a tangible membrane" in claim 1. The instant claims differ from the prior art in that Youssefyeh do not specifically teach a "membrane" as instantly claimed. However, they nonetheless teach that the topical formulation is deposited onto the desired area and allowed to *form a film*, which will allow for slow release of active agent onto the treatment area. Thus, the "film" taught by Youssefyeh is functionally equivalent to the "membrane" claimed by Applicant.

While the prior art does not explicitly teach treatment of "healed wounds", the prior art nonetheless explicitly teaches methods for treating inflammatory dermal conditions, both acute and chronic and teaches that suitable topical applications include film-forming preparations (see col. 13, line 53 – col. 14, line 40). The method comprises topical administration of safflower oil in combination with a corticosteroid and a pharmaceutically acceptable carrier, whereby upon application, the formulation is deposited on the skin to form a film for the release of active agent onto the treatment area. The methods of treatment and conditions to be treated as taught by Youssefyeh would include application upon healed wounds so as to reduce scarring and/or improve the appearance thereof.

Youssefyeh do not teach vitamin E, collagenase and treating a hypertrophic scar.

Lee ('162) teach a method for improving the size and appearance of a scar associated with fibromatosis, a keloid or a hypertrophic wound healing disorder that comprises stimulating collagenase activity in the scar. The method comprises covering the scar with a hydrogel or

thermally insulated material that elevates the surface temperature of the scar and that can contain a therapeutically effective amount of medicament (see Abstract); (column 1, lines 41-54); (col. 6, lines 17-49); (col. 11, lines 19-34).

Lee teaches that the collagenase is provided in the composition in order for the effective breakdown and degradation of collagen (col. 7, lines 44-62). Vitamins such as vitamin E are included in the composition (col. 11, lines 35-52).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide for methods for treating scars, such as hypertrophic scars such as taught by Lee within the methods of Youssefyeh. One would do so with a reasonable expectation of success because Lee explicitly teaches methods for improving the size and appearance of scars, including hypertrophic scars, which comprises applying a thermal material or hydrogel containing suitable ingredients such as vitamin E and collagenase, used for the degradation of collagen. The expected result would an enhanced method for treating dermatological disorders and conditions.

* * * * *

Claims 1-16 and 30-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mantelle (U.S. Pat. No. 5,446,070) in view of Lee (U.S. Pat. No. 5,552,162).

Mantelle ('070) teaches flexible, finite, bioadhesive compositions and methods for topical application comprising a therapeutically effective amount of a pharmaceutical agent(s), a pharmaceutically acceptable carrier and a solvent for the pharmaceutical agent(s) in the carrier and methods of administering the pharmaceutical agents (see Abstract); (col. 1, lines 18-34); (col. 4, line 24 – col. 5, line 62).

The composition when administered topically, for example to an area of the skin, delivers a pharmaceutical agent or a combination of agents to produce a local or systemic effect over a prolonged period of time (col. 5, line 65 – col. 6, line 3).

Suitable active agents disclosed for use in the invention include anti-inflammatory drugs, corticosteroids and the like (col. 23, line 32 – col. 41, line 39); claim 4; Examples 30-32.

Suitable adhesive carriers are disclosed at column 12, lines 55-65 and include cellulose derivatives, silicones.

Mantelle teaches the inclusion of enzymes, such as the proteolytic enzyme – collagenase (col. 38, line 4). Mantelle also teaches vitamins, such as vitamin E (col. 41, lines 35-36).

While the prior art does not explicitly teach treatment of "healed wounds", the prior art nonetheless explicitly teaches compositions that are topically applied on the skin for the effective treatment of pain. The method comprises applying a therapeutically effective amount of a pharmaceutical agent, a pharmaceutically acceptable carrier and a solvent for the pharmaceutical agent in the carrier. The compositions are suitable for topical application on the skin.

Mantelle does not teach treating a hypertrophic scar.

Lee ('162) teach a method for improving the size and appearance of a scar associated with fibromatosis, a keloid or a hypertrophic wound healing disorder that comprises stimulating collagenase activity in the scar. The method comprises covering the scar with a hydrogel or thermally insulated material that elevates the surface temperature of the scar and that can contain a therapeutically effective amount of medicament (see Abstract); (column 1, lines 41-54); (col. 6, lines 17-49); (col. 11, lines 19-34).

The compositions taught by Lee are particularly effective for improving the size and appearance of hypertrophic scars (see claim 7).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide for methods for treating scars, particularly hypertrophic scars such as taught by Lee within the methods of Mantelle. One would do so with a reasonable expectation of success because Lee explicitly teaches methods for improving the size and appearance of scars whereby the compositions are especially beneficial for improving hypertrophic scar formation. The expected result would an improved method for treating dermal skin conditions.

* * * * *

Response to Arguments

Applicant's arguments filed 05/07/08 have been fully considered but they are not persuasive.

- **35 U.S.C. §103(a) Rejection over Youssefyeh et al. (USPN 5,968,519) in view of Lee (USPN 5,552,162):**

Applicant argued, "Youseffyeh does not teach or suggest a method of treating healed wounds so as to reduce scarring and/or improve the appearance of scars. Youseffyeh teaches a method for the treatment of inflammation and pain associated with inflammatory dermatoses, which is a different condition than that of the present invention. Lee is directed to a method for improving the size and appearance of scar tissue. However, Lee does not teach or suggest the use of a fluid, film-forming carrier and hardening the carrier into a tangible membrane juxtaposed to the healed wound."

Applicant's arguments have been fully considered, but were not found persuasive. The secondary reference of Lee clearly resolves the deficiencies of the Youseffyeh primary reference in their teaching of a method for improving the size and appearance of scar tissue associated with keloids or hypertrophic wound healing disorders. See Abstract of Lee. Applicant argues that the "treatment of inflammation taught by Youseffyeh is a different condition than that of treating a healed wound so as to reduce scarring." However, Lee amply describes and teaches such a method of treating scars whereby a hydrogel is applied to cover the scar and teaches the same elements, used for the same purpose as that desired by Applicant. Thus, the references, in combination, address the same method of treatment using the same process steps employed by Applicant. Applicant also argues that "Scarring is not a form of inflammatory dermatoses." The Examiner notes however, that scarring, such as keloid formation, can occur as a result of inflammation, either mild or intense. Thus, it cannot be seen as to how the primary reference which teaches a method for the treatment of inflammation can be so far from the method of the instant invention, which aims to treat healed wounds (i.e., keloids), since inflammation can result in scar formation of keloids or hypertrophic scarring, for example. In any event, the Lee secondary reference vividly demonstrates the correlation between inflammation and scarring and demonstrates that it is well-known to simultaneously treat inflammatory conditions as well as scars, such as keloids, using their methods of scar treatment. Lee further explicitly teach the use of vitamin E and teach that cells that synthesize collagenase are influenced to a great extent by the environment in which they live. Lee teach that this includes cells of connective tissue and migratory cells that accumulate as a result of injury, *inflammation* or immune phenomena. See column 3, lines 58-67. Hence, it would be *prima facie* obvious to one of ordinary skill in the art

to use the secondary reference within the teachings of the primary reference because it would permit simultaneous treatment of two diseases or conditions (i.e., inflammation & scarring-keloids).

- **35 U.S.C. §103(a) Rejection over Mantelle (USPN 5,446,070) in view of Lee (USPN 5,552,162):**

Applicant argued, "Mantelle does not teach or suggest a method of treating healed wounds so as to reduce scarring and/or improve the appearance of scars. Lee is directed to a method for improving the size and appearance of scar tissue. However, Lee does not teach or suggest the use of a fluid, film-forming carrier and hardening the carrier into a tangible membrane juxtaposed to the healed wound."

Applicant's arguments have been considered, but were not deemed persuasive. Mantelle, as noted in the Office Action above, teach flexible, finite, bioadhesive compositions and methods for topical application, which comprise an active agent, pharmaceutically acceptable carrier and a solvent for the active agent in the carrier. Suitable active agents that are disclosed include anti-inflammatory drugs, corticosteroids and the like. See col. 23, line 32 – col. 41, line 39. While Mantelle does not teach treatment of a hypertrophic scar, the secondary reference of Lee clearly resolves this deficiency of the Mantelle primary reference. Lee amply describes and teaches such a method of treating scars, such as hypertrophic scars, whereby a hydrogel is applied to cover the scar. Lee teaches the same elements, used for the same purpose as that desired by Applicant. Thus, the references, in combination, address the same method of treatment using the same process steps employed by Applicant. It would be *prima facie* obvious to one of ordinary

skill in the art to use the secondary reference within the teachings of the primary reference because it would permit treatment of various diseases or conditions, such as hypertrophic scarring by topical application of pharmaceutically active agents that include anti-inflammatory agents (i.e., corticosteroids) taught by the cited prior art.

The rejections of record have been maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

--No claims are allowed at this time.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday, Tuesday, Thursday and Friday during regular business hours. (Wednesdays - Telework).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley, can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Humera N. Sheikh/

Primary Examiner, Art Unit 1618

hns

August 16, 2008